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FAQs on the CDC and FDA decision to "pause" administration of the Johnson & Johnson vaccines

Updated April 13, 2021

Situation updates

What happened with the Johnson & Johnson COVID-19 vaccine? Why are the Johnson & Johnson vaccines being "paused"?
Out of the 6.85 million doses of the Johnson and Johnson COVID-19 vaccine that have been administered in the United States, there have been 6 cases of people who got a rare type of blood clot after getting the Johnson & Johnson COVID-19 vaccine reported to the CDC's Vaccine Adverse Events Reporting System (VAERS). The CDC and FDA are recommending vaccine providers wait to give any more Johnson & Johnson vaccines, until they are able to give healthcare providers instructions on how to recognize and diagnose patients who may have this rare health problem, how to treat them appropriately, and to report any cases they feel may be related to the vaccine.

If these side effects are so rare, why do we need to pause administering the Johnson & Johnson vaccine?
We have had many questions about why they would pause vaccine administration, when only one in a million people have had this rare reaction to the vaccine. We have also been asked why they would pause vaccine administration when there are many medications— like oral contraceptives or birth control, as well as many others— that increase your risk for blood clots.

The blood clots these people got were a very rare, but severe, type of blood clot called cerebral venous sinus thrombosis (CVST) and were seen in combination with low levels of blood platelets (thrombocytopenia). Doctors have to treat these types of blood clots differently, with different medicine, than other blood clots. This condition is treatable, but doctors must know how to recognize it, how to report it, and how to treat it. Usually, the anticoagulant drug called

heparin is used to treat blood clots. In these cases, the use of heparin may be harmful, and alternative treatments need to be given.

The CDC and FDA want to wait before giving any more Johnson & Johnson vaccines, until we understand more about what happened and to make sure healthcare providers have all of the information they need to be able to effectively treat someone who may get this rare side effect. This pause is the right thing to do to ensure that happens. This is a good example of how the safety systems we have in place work to flag possible safety concerns for vaccines. Pausing Johnson & Johnson vaccine administration does not mean the vaccine is not safe for most people. It also does not mean that all or most of the people who have already received the Johnson & Johnson vaccine will get blood clots. These are RARE side effects. They are pausing the administration of this brand of vaccine because we want everyone to have all of the information, so they can make informed health decisions.

It is also important to point out that this recommendation to pause vaccine administration is only for the Johnson & Johnson vaccine, not the Pfizer or Moderna vaccines. There have been no reports of CVST with thrombocytopenia in people who got the Pfizer or Moderna vaccine.

How many people had this type of reaction to the Johnson & Johnson vaccine?
As of April 12, only 6 of the 6.85 million people in the United States who have gotten the Johnson & Johnshon vaccine have reported this type of reaction. The CDC and FDA are reviewing these cases of a rare and severe type of blood clot called called cerebral venous sinus thrombosis (CVST) and was seen in combination with low levels of blood platelets (thrombocytopenia) that was reported in 6 people after receiving the Johnson & Johnson vaccine. All 6 cases happened in women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination.

If I have an appointment for the J&J vaccine what should I do?
The Utah Department of Health has sent out an alert to all vaccine providers who have Johnson & Johnson vaccines asking them to pause administration until we receive more guidance from the FDA and CDC. Vaccine providers should be reaching out to you if your appointment is being impacted by this decision. If you haven't heard from them yet, please call your healthcare provider, vaccination location, or clinic to reschedule. Vaccination sites that don't have Pfizer or Moderna to substitute for Johnson & Johnson may ask you to reschedule your appointment for another time or see if you can get vaccinated at another location. If you would like to get a Pfizer or Moderna vaccine instead, you can find a vaccine provider at vaccinefinder.org or coronavirus.utah.gov.

The pause is a recommendation by the FDA and CDC for healthcare providers to use with most patients. However, if you and your healthcare provider determine the benefit of receiving the Johnson & Johnson vaccine to protect you from COVID-19 outweighs the risk of having a rare adverse reaction, your healthcare provider can still give the vaccine.

There have been no reports of CVST with thrombocytopenia in people who got the Pfizer or Moderna vaccine. If you have a vaccine appointment for the Pfizer or Moderna vaccines, please keep it. COVID-19 is a very serious virus, and can cause serious long-term health effects or even be deadly to many people. More than 1.9 million people have been hospitalized for severe illness and more than 556,000 people have died from the virus, just in the United States alone. There is no way to know if you will experience severe illness from COVID-19. The benefits of getting vaccinated outweigh the risks for most people.

Is it normal for the FDA and CDC to pause the distribution of a vaccine?
We take vaccine safety very seriously in the United States. Whenever a possible serious adverse effect of vaccination is reported, we investigate it. Transparency is key and we want to tell people what we know, when we know it, how we got the information, and what we're doing to find out more. We have a safety measure in place to help public health, healthcare providers, and scientists understand any problems possibly related to vaccinations. It's normal to temporarily pause clinical trials or distribution of vaccines or medications if data tells us there may be something that needs further investigation. **This is done to protect people from harmful side effects and to make sure communities impacted the most by a disease - or in this case, the pandemic - do not suffer from further inequities.** If someone gets a vaccine and has an adverse event after vaccination, the healthcare provider or the person who got vaccinated can report the adverse event to the CDC's Vaccine Adverse Event Reporting System (VAERS). This means that anyone who has gotten a vaccine, not just healthcare providers, can report any side effect he or she thinks may be related to the vaccine. The VAERS system is set up like this to make sure we have as much information as possible to study, and is why public health can confidently give vaccine recommendations.

Vaccines are monitored so closely in the United States, that we know mild or moderate side effects, like a fever or sore arm, are normal after any vaccination. We also know that severe side effects from vaccination are very rare. Monitoring vaccines so closely lets us not only be confident that vaccines are safe, but also lets us give good recommendations to healthcare providers for things to watch for, as well as the best ways to treat rare, severe side effects from vaccination.

The CDC and FDA want to wait before giving any more Johnson & Johnson vaccines, until we understand more about what happened and to make sure healthcare providers have all of the information they need to be able to effectively treat someone who may get this rare health problem. This condition is treatable, but doctors must know how to recognize it, how to report it, and how to treat it. Usually, the anticoagulant drug called heparin is used to treat blood clots. In these cases, the use of heparin may be harmful, and alternative treatments need to be given.

There have been no reports of CVST with thrombocytopenia in people who got the Pfizer or Moderna vaccine. If you have a vaccine appointment for the Pfizer or Moderna vaccines, please keep it. COVID-19 is a very serious virus, and can cause serious long-term health effects or even be deadly to many people. More than 1.9 million people have been hospitalized for severe illness and more than 556,000 people have died from the virus, just in the United States alone.

There is no way to know if you will experience severe illness from COVID-19. The benefits of getting vaccinated outweigh the risks for most people.

What happens next?
The Advisory Committee on Immunization Practices (ACIP) will meet on Wednesday, April 14, to review the 6 cases and will revise the fact sheet concerning the Johnson & Johnson vaccine to include symptoms of this rare condition and tell healthcare providers how to effectively treat it.

How long will the "pause" be?
We don't know yet. The CDC and FDA think it may only take a few days to weeks to complete the investigation into these cases and have the best recommendations for healthcare providers and people who get the Johnson & Johnson vaccine.

Where can I get more information on this situation?

- Joint statement from the CDC and FDA about the Johnson & Johnson vaccines: https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html
- CDC Health Alert Network: https://emergency.cdc.gov/han/2021/han00442.asp
- Press conference with the FDA and CDC discussing these rare events and decision to pause administration of the Johnson & Johnson vaccines: https://www.youtube.com/watch?v=_ELXnGYgsJY

For people who have already received the Johnson & Johnson vaccine or who have an appointment for this vaccine

What should I watch for if I received the Johnson & Johnson vaccine? When should I be worried or get medical care?
Doctors say it is normal for you to get mild to moderate flu-like symptoms, including a headache, one or two days after receiving the Johnson & Johnson vaccine. **If you received the Johnson & Johnson vaccine more than a month ago, the risk of having a severe reaction is very low at this time.** However, if you had a Johnson & Johnson vaccine in the last 3 weeks, you should be aware of these symptoms. If you get any of the following symptoms, call your healthcare provider, or go to the emergency room or urgent care. Let your healthcare providers know that you recently received the Johnson & Johnson vaccine.

- Severe headache
- Backache
- New neurologic symptoms
- Severe abdominal pain
- Shortness of breath
- Leg swelling
- Petechiae (tiny red spots on the skin)
- Or new or easy bruising

How do I tell the difference between normal side effects and more serious ones after vaccination that require medical care?
It's common to have mild or moderate side effects after you get any vaccination. This means your body has started to create an immune response and is learning to fight the virus. Side effects like a sore arm, fever, achy body, or a headache are normal after you get a vaccine. These reactions usually happen within the first 24-48 hours after you get a vaccine. These side effects can affect your daily activities, but go away after a few days. Severe allergic reactions after receiving a COVID-19 vaccination are rare and usually occur within minutes to hours after vaccination.

The side effects we are concerned about with the Johnson & Johnson vaccine are different and happened between 6 and 13 days after the person received the Johnson & Johnson vaccine. If you received the Johnson & Johnson vaccine more than a month ago, your risk for severe reactions is very low.

However, if you were vaccinated in the last 3 weeks with a Johnson & Johnson vaccine and get any of the following symptoms, call your healthcare provider, or go to the emergency room or urgent care. Let your healthcare providers know that you recently received the Johnson & Johnson vaccine.

- Severe headache
- Backache
- New neurologic symptoms
- Severe abdominal pain
- Shortness of breath
- Leg swelling
- Petechiae (tiny red spots on the skin)
- Or new or easy bruising

Should I report any side effects after I get vaccinated for COVID-19?
We take vaccine safety very seriously in the United States. If you get a vaccine and have an adverse event after vaccination, like a health problem or symptom you didn't have before getting vaccinated, you or your healthcare provider can report the adverse event to the CDC's Vaccine Adverse Event Reporting System (VAERS). This means that anyone who has gotten a vaccine, not just healthcare providers, can report any side effect you think may be related to the vaccine. The VAERS system is set up like this to make sure we have as much information as possible to study, and is why public health can confidently give vaccine recommendations.

If you aren't sure if you should report a side effect or have questions, call a healthcare provider. You may also call the Utah Poison Control Center at 1-800-222-1222. They have poison specialists available 24 hours a day 7 days a week to help answer questions about whether you need to report a side effect to VAERS or potentially seek medical care.

Vaccines are monitored so closely in the United States, that we know mild or moderate side effects, like a fever or sore arm, are normal after any vaccination. We also know that severe side effects from vaccination are very rare. Monitoring vaccines so closely lets us not only be confident that vaccines are safe, but also lets us give good recommendations to healthcare providers for things to watch for, as well as the best ways to treat rare, severe side effects after vaccination.

Whenever a possible serious adverse effect of vaccination is reported, it's investigated. Transparency is key and we want to tell people what we know, when we know it, how we got the information and what we're doing to find out more. We have a safety measure in place to help public health, healthcare providers, and scientists understand any problems possibly related to vaccinations.

How many appointments in Utah will be impacted by this?
Johnson & Johnson vaccines make up only about 7% of the total vaccines delivered in Utah right now. We were supposed to receive 4,900 doses of the Johnson & Johnson vaccine this week. Those appointments will need to be rescheduled, or people who had these appointments can get the Pfizer or Moderna vaccines instead.

For people who have received the Pfizer or Moderna vaccines or who have appointments for these vaccines

Are the Pfizer and Moderna vaccines paused too?
No. There have been no reports of CVST with thrombocytopenia in people who got the Pfizer or Moderna vaccine. If you have a vaccine appointment for the Pfizer or Moderna vaccines, please keep it. COVID-19 is a very serious virus, and can cause serious long-term health effects or even be deadly to many people. More than 1.9 million people have been hospitalized for severe illness and more than 556,000 people have died from the virus, just in the United States alone. There is no way to know if you will experience severe illness from COVID-19. The benefits of getting vaccinated outweigh the risks for most people.

This recommendation to pause vaccine administration is only for the Johnson & Johnson vaccine, not the Pfizer or Moderna vaccines. Johnson & Johnson vaccines make up only about 7% of the total vaccines delivered in Utah right now.

Are the Pfizer and Moderna vaccines the same kind of vaccine that Johnson & Johnson is?
No. The Pfizer and Moderna vaccines are mRNA vaccines. You can learn more about mRNA vaccines here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mRNA.html.

The Johnson & Johnson vaccine is a type of adenoviral vector or viral vector vaccine. You can learn more about a viral vector vaccine here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html.

Should I keep my appointment if I am supposed to get the Pfizer or Moderna vaccine?
Yes. There have been no reports of CVST with thrombocytopenia in people who got the Pfizer or Moderna vaccine. If you have a vaccine appointment for the Pfizer or Moderna vaccines, please keep it. COVID-19 is a very serious virus, and can cause serious long-term health effects or even be deadly to many people. More than 1.9 million people have been hospitalized for severe illness and more than 556,000 people have died from the virus, just in the United States alone. There is no way to know if you will experience severe illness from COVID-19. The benefits of getting vaccinated outweigh the risks for most people.

Where can I get a Pfizer or Moderna vaccine instead?
You can find a vaccine location near you at https://coronavirus.utah.gov/vaccine-distribution/.

For healthcare providers

What should I do if I have a patient with these symptoms who received the Johnson & Johnson vaccine?
We are reaching out to healthcare providers to make sure they are aware of the importance of monitoring patients closely for severe headaches, plus CVST AND low platelets, and that they may need to use different treatment than they may typically use in these situations.

Providers should monitor patients who have recently received the Johnson & Johnson COVID-19 vaccine closely for symptoms that could be signs of serious thrombotic events or thrombocytopenia.

- Severe headache
- Backache
- New neurologic symptoms
- Severe abdominal pain
- Shortness of breath
- Leg swelling
- Petechiae (tiny red spots on the skin)
- Or new or easy bruising

It is important for healthcare providers to be aware that treatment for a patient who gets these specific types of blood clots following Johnson & Johnson COVID-19 vaccination is different from how the provider might typically treat blood clots. Usually, the anticoagulant drug called heparin is used to treat blood clots. In these cases, the use of heparin may be harmful, and alternative treatments need to be given. Providers should get platelet counts and screen patients for signs of immune thrombotic thrombocytopenia.

It is strongly recommended providers follow screening guidelines from the HAN message and consult with a hematologist for patients with a thrombotic event and thrombocytopenia after the Johnson & Johnson COVID-19 vaccine.

These reports following the Johnson & Johnson COVID-19 vaccine are similar to reports of thrombotic events with thrombocytopenia after receipt of the AstraZeneca COVID-19 vaccine in Europe.

Studies of patients in Europe who were diagnosed with immune thrombotic thrombocytopenia after having the AstraZeneca COVID-19 vaccine, indicate these rare and unusual adverse events after vaccination may be associated with platelet-activating antibodies against platelet factor-4 (PF4), a type of protein. Usually, the anticoagulant drug called heparin is used to treat blood clots. In this setting, the use of heparin may be harmful, and alternative treatments need to be given.

We will likely have more clinical guidance after the ACIP meets so you'll be able to continue to safely administer the Johnson & Johnson vaccine to patients. It's too early to know if vaccination and screening will change as a result of this pause. We know that you are as committed to the safety of your patients as we are.

Where can I get more information on this situation?

- Joint statement from the CDC and FDA about the Johnson & Johnson vaccines: https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html
- CDC Health Alert Network notice, Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine: https://emergency.cdc.gov/han/2021/han00442.asp
- Press conference with the FDA and CDC discussing these rare events and decision to pause administration of the Johnson & Johnson vaccines: https://www.youtube.com/watch?v=_ELXnGYgsJY